



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

DATE: November 23, 2021

SUBJECT: Efficacy Review for Behr Sanitizing Paint,
EPA Reg. No. 32273-RN
Action Code Case: 00299430
E-submission No. 63037

FROM: Nicole Karikari
Efficacy Branch *Nicole Karikari*
Antimicrobials Division (7510P)
Date Signed: November 23, 2021

THRU: Tajah L. Blackburn, Ph.D.
Senior Scientist *[Signature]*
Efficacy Branch
Antimicrobials Division (7510P)
Date Signed: November 16, 2021

TO: Eric Miederhoff, PM 31/ Aiden Fife
Regulatory Management Branch I
Antimicrobials Division (7510P)

APPLICANT: Behr Process Corporation
1801 E. St. Andrew Place
Santa Ana, CA 92705

Formulation from the Label:

| <u>Active Ingredient(s)</u> | <u>% by wt.</u> |
|--------------------------------|-----------------|
| Cupric Oxide..... | 0.351% |
| <u>Other Ingredients</u> | 99.649% |
| Total..... | 100.000% |

I BACKGROUND

Product Description (as packaged, as applied): Architectural coating/ paint

Submission type: New Registration

Currently registered efficacy claim(s): N/A

Requested action(s): Applicant is submitting efficacy data to support the registration of antimicrobial architectural coatings (i.e., walls, other painted surfaces) with multi-year supplemental antimicrobial residual efficacy claims against *S. aureus*, *P. aeruginosa*, Feline Calicivirus, and SARS-CoV-2.

Documents considered in this review:

- Cover letter from applicant to EPA dated 4/28/2021
- Transmittal Document dated 4/28/2021
- Proposed label dated 4/23/2021
- Data Matrix (EPA Form 8570-35) dated 8/22/2021
- Five efficacy studies
 - MRID 51549609
 - MRID 51549610
 - MRID 51549611
 - MRID 51549612
 - MRID 51665601 – Simulated Wear Regimen (Amended Report)
- Confidential Statement of Formula (EPA Form 8670-4)
 - Basic Formulation dated 4/28/2021
 - Alternative Formulations 1 through 7 dated 4/28/2021
- Correspondence from Agency (T. Blackburn) to registrant dated 4/11/2021
- Correspondence from Agency (K. Willis) to registrant dated 4/26/2021
- Correspondence from Kronos, Inc. (D. Givens) – Re: Communication with Agency (Inerts Branch/ K. Leifer) dated 4/19/2021
- Response letter from registrant to the Agency regarding efficacy technical screen deficiencies dated 8/25/2021

II PROPOSED DIRECTIONS FOR USE

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

SURFACE PREPARATION†

- All surfaces should be clean, free of dust, chalk, oil, grease, wax, polish, mold and mildew stains, loose and peeling paint, rust, and all other foreign substances. Scuff sand glossy surfaces and repair imperfections. Allow new concrete, plaster and masonry to cure for 30 days before painting.
- Although this product is a paint & primer (self-priming - first coat is the primer and the second coat is the finish) over most properly prepared surfaces, certain substrate and exposure

conditions, as well as project requirements, may necessitate the use of substrate-specific or solution-driven primers.

†ATTENTION If you scrape, sand or remove old paint, you may release lead dust. LEAD IS TOXIC. EXPOSURE TO LEAD DUST CAN CAUSE SERIOUS ILLNESS, SUCH AS BRAIN DAMAGE, ESPECIALLY IN CHILDREN. PREGNANT WOMEN SHOULD ALSO AVOID EXPOSURE. Wear a NIOSH-approved respirator to control lead exposure. Clean up carefully with a HEPA vacuum and a wet mop. Before you start, find out how to protect yourself and your family by contacting the National Lead Information Center at 1-800-424-LEAD or log on to www.epa.gov/lead.

APPLICATION

- For best results, apply when air, material and surface temperatures are between 50°F and 90°F.
- Stir paint occasionally. Intermix containers of same product to ensure color and sheen uniformity.
- Do not thin. Product is formulated at package consistency.
- Apply two coats by brush (nylon/polyester), roller (3/8" – 1/2" nap) or airless sprayer (.015" – .019" spray tip) at a coverage of 250 – 400 sq ft per gallon. Coverage depends on application method and substrate porosity. Certain colors may require additional coats for complete hide.
- Dries to touch in 1 hour; recoat after 2 hours @ 77°F and 50% RH. Drying and recoat times are dependent on temperature, humidity and film thickness.
- Clean all tools and equipment with soap and water.
- [CONTAINS: CRYSTALLINE SILICA and TITANIUM DIOXIDE. USE ONLY WITH ADEQUATE VENTILATION.] To avoid breathing vapors and spray mist, open windows and doors or use other means to ensure fresh air entry during application and drying. If you experience eye watering, headache or dizziness, increase fresh air. If properly used, a respirator (NIOSH approved for organic vapor with P series particulate pre-filter) may offer additional protection; obtain professional advice before using. A dust mask does not provide protection against vapors.

SURFACE CARE AND MAINTENANCE

Periodic cleaning to remove dirt and stains is necessary for good sanitization and to assure the effective virucidal and microbicidal performance of the surface. Cleaning does not reduce the virucidal and microbicidal performance of the painted surface. To ensure continuous protection, repaint surface if film becomes damaged (peeled, cracked, etc.) or if paint becomes covered with oils, grease, wax, other paints and other foreign substances; or within 6 years.

Proper Surface Care and Use: The use of an antimicrobial treated surface is a supplement to and not a substitute for standard infection control practices; user must continue to follow all current infection control practices, including those practices related to cleaning and disinfection of environmental surfaces. The painted surface material has been shown to reduce microbial contamination but does not necessarily prevent cross contamination.

Cleaning Directions: Cleaning agents typically used on painted surfaces are acceptable. The appropriate cleaning agent depends on the type of soiling and the measure of sanitization required. The best way to wash painted surfaces is to use a soft damp cloth or sponge and a mild detergent solution (a small amount of dishwashing liquid in water). Gently wipe the soiled area (using the least amount of pressure) until the stain is removed. Allow the cleaning solution to do the work. Do not scrub the surface as this can actually cause the stain to spread. Rinse

surface with clean water. Do not use harsh or abrasive cleansers or pads, which can scratch, burnish or damage the paint film. Consider using BEHR SWIPES® Interior Wall Wipes for removing stubborn stains, such as lipstick and crayon. **DO NOT USE OXIDIZING CLEANERS, SUCH AS BLEACH, OR ENZYME-BASED CLEANING SOLUTIONS AS THEY WILL CAUSE DISCOLORATION AND REDUCE THE EFFICACY OF THE SURFACE.**

III AGENCY STANDARDS

Interim Guidance – Review for Products Adding Residual Efficacy Claims

(<https://www.epa.gov/pesticide-registration/interim-guidance-review-products-adding-residual-efficacy-claims> - Last modified: April 28, 2021)

Supplemental Residual Antimicrobial Products

III. Qualifying antimicrobial surface coatings, films, fixed/solid and paint products should demonstrate efficacy against vegetative bacteria first before virus claims can be supported. These products are not required to meet the efficacy standards for disinfectants and can only be approved for use as supplements to standard disinfection. The duration of residual effectiveness claims that EPA will consider for review depends on the type of product as detailed below.

A. Antimicrobial Surface Coatings and Films

Utilize EPA's draft [Performance of Antimicrobial Surface Coatings on Hard Non-porous Surfaces](#) for qualifying bacteria. Additional information is provided below for addition of virus claims.

Test Organisms

Bacteria—*Staphylococcus aureus* (ATCC No. 6538) and *Pseudomonas aeruginosa* (ATCC No. 15442) are the qualifying bacteria required to support supplemental residual antimicrobial surface claims for the proposed claim duration (e.g., 1 week, 2 weeks, etc.)

Testing should be conducted on 3 product lots per bacterium at the LCL.

To support claims for additional bacteria, testing should be conducted according to the method but with a reduced number of product lots.

2 lots of product for each bacterium at the nominal concentration.

Viruses—All viruses for which claims are desired should be tested. The most difficult to kill virus should be subjected to the durability assessment using coating carriers followed by the efficacy assessment to support the proposed duration (e.g., 1 week, 2 weeks, etc.). All other viruses should be tested using coated carriers that were not subjected to the durability procedure.

Assessment of virucidal efficacy on the coated carriers should be conducted consistent with ASTM E1053, the standard method specified in [EPA's 810.2200 Efficacy Test Guideline](#).

Two lots of product at the LCL should be tested for the most difficult to kill virus. Two lots of product at the nominal concentration should be tested for additional viruses.

Note that to be considered as a supplement to List N, virus testing should include a non-enveloped virus or a human coronavirus (SARS-CoV-2 or human coronavirus 229E).

Stainless steel carriers will be used to support claims for coatings on hard, nonporous surface. Use sites should be limited to hard, non-porous surfaces. Additional material types (e.g., porous materials or textiles) may be proposed by the registrant upon consultation with EPA prior to submission.

The recommended number of abrasions (touches) and cycles of exposure to cleaning or disinfecting chemicals are provided in the method in order to substantiate durability claims. The method also specifies the chemical disinfecting solutions to simulate cycles of in-service disinfection and cleaning. Additional details can be found in the method.

10 cycles of abrasion/chemical exposure = 1 week of durability. The number of cycles can be increased in 1 week increments to support claims up to 4-weeks.

If a product is incompatible with one or more of the test chemistries, this should be discussed with EPA in advance and may limit use sites and surfaces depending on the nature of the incompatibility. EPA does not have a standard method for determining incompatibility. This may be based on research and development data or known incompatibilities with the coating material for example.

This protocol can be modified for films upon consultation with EPA in advance of submission.

If you intend to claim supplemental residual effects longer than 4-weeks, consult with EPA in advance of submission. Because the on-going antimicrobial integrity of coatings and films will not be readily visible, it is important that end users have a reasonable expectation of durability.

Products should achieve a 99.9% reduction (3-log) for both bacteria and virus/es in comparison to untreated controls within a maximum of 2-hours but not less than 1-hour, as EPA is concerned that observations taken before the inoculum has dried (e.g., less than 1 hour) on the surface may not provide an accurate assessment of the product.

The time to achieve performance begins at the time of inoculation.

B. Antimicrobial Surface Coatings and Films - Labeling and Additional Information

This new category of antimicrobial products should be labeled as supplemental residual antimicrobial surfaces.

As these products do not meet the criteria for a disinfectant due to the longer contact time and lower performance standard, claims for residual disinfectant are not acceptable. As above, contact times for disinfectants are ≤ 10 minutes and with a higher performance standard for bacteria.

Products should carry the following prominent label qualifier that they are a supplement to standard disinfection and cleaning:

“Although this product DOES NOT meet EPA’s standards for disinfectants, EPA has determined that, when used with an EPA-registered disinfectant, this product can provide some additional protection against [microorganism(s)] for up to X days. This product DOES NOT achieve the

same level of efficacy as an EPA-registered disinfectant; it is only intended to provide supplemental protection between routine applications of EPA-registered disinfectants.”

For products eligible only for supplemental residual antimicrobial claims, EPA intends to require as a term of registration that the label and labelling state “This product does not meet EPA’s efficacy standards to qualify as a stand-alone disinfectant”.

Although these products will not be eligible for List N, they will be eligible as a supplement to List N (N.1) to reflect that they are supplemental treatments (i.e., not stand-alone disinfectants) and intended for use in combination with List N disinfectants.

The following are example acceptable product label claims:

“Kills 99.9% of [insert microorganism/s] within 2 hours of exposure when used as part of a comprehensive infection control program/protocol for up to X days.”

“Continuously reduces [insert microorganism/s] within 2 hours of exposure when used as part of a comprehensive infection control program for up to X days.”

C. Fixed/Solid Surfaces Including Solid Copper and Other Metals and Solid Impregnated Materials and Paints- Method Recommendation

Utilize EPA’s [Draft Copper Surface Protocol](#) for qualifying bacteria. Additional information is provided below for addition of virus claims.

Test Organisms

Bacteria—*Staphylococcus aureus* (ATCC No. 6538) and *Pseudomonas aeruginosa* (ATCC No. 15442) are the qualifying bacteria used to support supplemental residual surface claims.

Testing should be conducted on 3 product lots per bacterium at the LCL.

To support claims for additional bacteria, testing should be conducted according to the method but with a reduced number of product lots.

2 lots of product for each bacterium at the nominal concentration.

Viruses—All viruses for which claims are desired should be tested. The most difficult to kill virus should be subjected to the durability assessment in the copper method followed by the efficacy assessment. All other viruses should be tested using test carriers that were not subjected to the durability procedure.

Assessment of virucidal efficacy on the coated carriers should be conducted consistent with ASTM E1053, the standard method specified in [EPA’s 810.2200 Efficacy Test Guideline](#)

Two lots of product at the LCL should be tested for the most difficult to kill virus. Two lots of product at the nominal concentration should be tested for additional viruses.

The recommended number of abrasions (touches) and cycles of exposure to cleaning or disinfecting chemicals are provided in the method in order to substantiate durability claims. The method also specifies the chemical solutions to simulate cycles of disinfection and cleaning.

As the durability of these types of product can be readily observed, duration claims are not necessary. This is consistent with currently registered copper-containing surface products and paints.

If a product is incompatible with one or more of the test chemistries, this should be discussed with EPA in advance and may limit use sites and surfaces depending on the nature of the incompatibility. EPA does not have a standard method for determining incompatibility. This may be based on research and development data or known incompatibilities with the coating material for example.

This protocol can be modified for other metals or solid impregnated surfaces or paints upon consultation with EPA.

Products should achieve a 99.9% reduction (3-log) for both bacteria and virus/es in comparison to untreated controls within 2-hours.

The time to achieve performance begins at the time of inoculation.

D. Fixed/Solid Surfaces Including Solid Copper and Other Metals and Solid Impregnated Materials and Paints- Labeling and additional information

These products should be labeled as supplemental residual antimicrobial surfaces.

As these products do not meet the criteria for a disinfectant due to the longer contact time and lower performance standard, claims for residual disinfectant are not acceptable.

Products should carry the following prominent label qualifier that they are a supplement to standard disinfection and cleaning:

“Although this product DOES NOT meet EPA’s standards for disinfectants, EPA has determined that, when used with an EPA-registered disinfectant, this product can provide some additional protection against [microorganism(s)] for up to X days. This product DOES NOT achieve the same level of efficacy as an EPA-registered disinfectant; it is only intended to provide supplemental protection between routine applications of EPA-registered disinfectants.”

For products eligible only for supplemental residual antimicrobial claims, EPA intends to require as a term of registration that the label and labelling should state “This product does not meet EPA’s efficacy standards to qualify as a stand-alone disinfectant”.

Although these products will not be eligible for List N, they will be eligible as a supplement to List N (N.1) to reflect that they are supplemental treatments (i.e., not stand-alone disinfectants) and intended for use in combination with List N disinfectants. The following are example acceptable product label claims:

“Kills 99.9% of [insert microorganism/s] within 2 hours of exposure when used as part of a comprehensive infection control program/protocol”

“Continuously reduces [insert microorganism/s] within 2 hours of exposure when used as part of a comprehensive infection control program”

E. Supplemental Residual Antimicrobial Products - Stewardship Program

EPA intends to require, as a term of registration, that registrants of all supplemental residual antimicrobial products prepare and implement a written stewardship plan designed to support the responsible use of supplemental residual coatings and antimicrobial surface products. Unlike the conventional antimicrobial products, these products represent unique challenges that require timely feedback to ensure proper use and compatibility in combination with current infection control practices. EPA expects that plans would be submitted for EPA review and approval during the registration process, or shortly thereafter (e.g., within two months after the registration date). An approvable plan would address the proper sale (including advertising and promotional materials), distribution, and responsible use of the supplemental residual coatings and antimicrobial surface products. Plans should include, at a minimum, the following elements:

Advertising and promotional materials that clearly and consistently include a disclaimer that the product does not meet EPA's standards for disinfectants and is intended to supplement the use of EPA-registered disinfectants.

Outreach to the infection control community;

Customer feedback consisting of product issues/concerns, adverse events, compliance challenges/observations, and contraindications/adverse events gathered through quarterly registrant-initiated surveys, customer complaints, and suggestion boards; and

Development of a stewardship website

If EPA determines at any time following registration that the Plan is not being adequately or timely implemented or does not effectively ensure the product's safe and effective use, the registration may be cancelled by the Agency.

IV STUDY SUMMARIES

Post-Test Chemical Analysis of the Test Samples:

Certificates of Analysis (CoA) with chemical analyses reflecting a date before the efficacy testing per the 810 guidelines) for each of the tinted product lots tested in all the submitted efficacy studies as it relates to the subject product and its active ingredients were not submitted by Behr Process Corporation. However, in response to the Efficacy Technical Screen of the original data submission, the Applicant provided the post-efficacy testing chemical analyses of the test samples via CDX on October 5, 2021.

Proposed Confidential Statement of Formula (EPA Form 8670-4) – Basic Formulation dated 4/28/2021

| | |
|---|--|
| Active Ingredient | Corning® Antimicrobial Particles Cupric Oxide (CASRN 1317-38-0) (33% active) |
| Nominal (Actual Percent by weight) | 0.351 |
| Lower Certified Limit (Actual Percent by weight) | 0.3159 |
| Acceptable Level (Based on EPA Standard Certified Limits) | 0.322218 |

Lot 1. Post-test chemical analysis of test lots

| Formulation ID | Tint and Treatment | ID Code in MRID 51549611 and 51549612 | ID Code in MRID 51549609 | ID Code in MRID 51549610 | Date Tested - Base Formulation | Date Tested - Base Formulation with Colorant | Post-test CuO (wt%) | Post-test analysis at LCL? |
|--|----------------------|---|--------------------------|---|--------------------------------|--|---------------------|----------------------------|
| 150036-2050-CUGLASS, vers. EX 51 | Untinted with Copper | Eggshell Base Paint | 2190 | 2190 (Eggshell, Treated, untinted) | 3/26/2021 | N/A | 0.266 | Yes |
| 150036-2050-CUGLASS, vers. EX 51, with colorant BL | Tinted with Copper | Eggshell Base Paint with carbon black pigment | 2190-B | 2190-B (Eggshell, with Carbon Black) | 3/26/2021 | 9/16/2021 | 0.250 | Yes |
| 150036-2050-CUGLASS, vers. EX 51, with colorant EL | Tinted with Copper | Eggshell Base Paint with organic pigment | 2190-O | 2190-O (Eggshell, Organic) | 3/26/2021 | 9/16/2021 | 0.342 | No |
| 150036-2050-CUGLASS, vers. EX 51, with colorant CL | Tinted with Copper | Eggshell Base Paint with inorganic pigment | 2190-I | 2190-I (Eggshell, Inorganic) | 3/26/2021 | 9/16/2021 | 0.245 | Yes |
| 150036-3300-CU, EX 21 | Untinted with Copper | Semi-Gloss Deep Paint | 3193 | 3193 - Semi-Gloss Deep, treated, untinted) (identified on page 14 of study as "tinted") | 3/26/2021 | N/A | 0.286 | Yes |

Lot 2. Post-test chemical analysis of test lots

| Formulation ID | Tint and Treatment | ID Code in MRID 51549611 and 51549612 | ID Code in MRID 51549609 | ID Code in MRID 51549610 | Date Tested - Base Formulation | Date Tested - Base Formulation with Colorant | Post-test CuO (wt%) | Post-test analysis at LCL? |
|----------------------------------|----------------------|---------------------------------------|--------------------------|------------------------------------|--------------------------------|--|---------------------|----------------------------|
| 150036-2050-CUGLASS, vers. EX 51 | Untinted with Copper | Eggshell Base Paint | 2190 | 2190 (Eggshell, Treated, untinted) | 3/26/2021 | N/A | 0.291 | Yes |

| | | | | | | | | |
|--|----------------------|---|--------|---|-----------|-----------|-------|-----|
| 150036-2050-CUGLASS, vers. EX 51, with colorant BL | Tinted with Copper | Eggshell Base Paint with carbon black pigment | 2190-B | 2190-B (Eggshell, with Carbon Black) | 3/26/2021 | 9/16/2021 | 0.273 | Yes |
| 150036-2050-CUGLASS, vers. EX 51, with colorant EL | Tinted with Copper | Eggshell Base Paint with organic pigment | 2190-O | 2190-O (Eggshell, Organic) | 3/26/2021 | 9/16/2021 | 0.365 | No |
| 150036-2050-CUGLASS, vers. EX 51, with colorant CL | Tinted with Copper | Eggshell Base Paint with inorganic pigment | 2190-I | 2190-I (Eggshell, Inorganic) | 3/26/2021 | 9/16/2021 | 0.268 | Yes |
| 150036-3300-CU, EX 21 | Untinted with Copper | Semi-Gloss Deep Paint | 3193 | 3193 - Semi-Gloss Deep, treated, untinted) (identified on page 14 of study as "tinted") | 3/26/2021 | N/A | 0.322 | Yes |

Basic CSF dated 4/28/2021 indicated that the Lower Certified Limit (LCL) of the subject product as 0.3159 (Acceptable Level = 0.322218%).

Abrasion and Exposure to Chemical Solutions Treatments:

Per MRID 51665601: *“The underlying protocol for the efficacy data, Corning protocol MRID #51141402 Protocol for Measuring Virucidal Efficacy of AM Paints, identifies a simulated wear procedure in support of residual efficacy claims for the product that involves exposing the product to different cleaning chemicals to simulate cleaning. This document sets out the procedure followed by Behr to prepare the test carriers for the studies.”*

“The Simulated Wear testing protocol of Corning was followed and is described below. Simulated wear cycling was initiated after the final coat of paint on each test panel had been allowed to cure for at least 24 hours. The wear procedure was intended to simulate cleaning of a vertical surface; therefore, relatively low volumes of cleaner were applied to the test panels at a rate where the cleaner would not drip down to the floor if applied to a vertical surface.

The wear exposure was performed with a Gardco, Model D10V (or equivalent) abrasion tester. The weight of the fully assembled abrasion boat (Gardco WA-2225) was between 1000g and 1085g. See Figure 1 in Appendix.

Exposed panels underwent wear testing at 72 cycles per panel, where one cycle equals two passes over the carrier (over and back). The weight of the boat was 1015 g.

The cleaning solution was prepared using Best Yet™ citrus cleaner [EPA Reg. No. 5429-22; Active Ingredient: Quaternary Compound] or Steris Coverage Plus NPD [EPA Reg. No. 6836-139-1043; Active Ingredient: Quaternary Compound] (see Figures 3 and 4 in Appendix) following the manufacturer’s recommended dilution ratio per instructions on the label (59.14 mL of detergent was added to 3726 mL of cold tap water). The appropriate test or control panel was placed on the Gardco Washability Tester tray.”

The cleaners used were:

Best Yet™ citrus cleaner (Cello Cleaner-Disinfectant Deodorant) – EPA Reg. No. 5429-22
(Identified as Cleaner 1 per MRID 51665601 – Simulated Wear Regimen (Amended Report))

Active Ingredients (per label dated 3/24/2021:

| | |
|--|--------|
| Sodium Carbonate..... | 3.0% |
| n-Akyl (60% C14, 30% C16, 5% C12, 5% C18) dimethyl benzyl ammonium chlorides..... | 1.6% |
| n-Akyl (68% C12, 32% C14) dimethyl ethylbenzyl ammonium chlorides..... | 1.6% |
| Other Ingredients..... | 93.8% |
| Total..... | 100.0% |

Steris Coverage Plus NPD – EPA Reg. No. 6836-139-1043

(Identified as Cleaner 2 per MRID 51665601 – Simulated Wear Regimen (Amended Report))

Active Ingredients (per label dated 3/24/2021:

| | |
|---|--------|
| Octyl decyl dimethyl ammonium chloride..... | 6.510% |
| Dioctyl dimethyl ammonium chloride..... | 2.604% |
| Didecyl dimethyl ammonium chloride..... | 3.906% |

| | |
|--|----------|
| Akyl (C14, 50%; C12, 40%; C16, 10%) dimethyl benzyl ammonium chloride..... | 8.680% |
| Other Ingredients..... | 78.300% |
| Total..... | 100.000% |

Per MRID 52665601: “The cleaning solution was prepared using Best Yet™ citrus cleaner or Steris Coverage Plus NPD (see Figures 3 and 4 in the Appendix) following the manufacturer's recommended dilution ratio per instructions on the label (59.14 ml of detergent was added to 3726 ml of cold tap water). The appropriate test or control panel was placed on the Gardco Washability Tester tray.”

“A common non-abrasive sponge (see Figure 1) was soaked in the prepared cleaner solution prior to the initial simulated wear cycle. The test or control panel was placed on the Gardco D10V abrasion tester. The sponge was removed from the cleaning solution and excess solution was wrung out. The sponge was positioned under the fully assembled abrasion boat that weighed 1015 g, within the 1000 g – 1085 g range specified in the protocol.”

“After the wear cycle was completed, the boat and sponge were removed. The sponge was discarded and a new sponge was placed into the cleaning solution. The panel was removed from the Gardco Washability Tester and placed on a horizontal surface and allowed to dry before starting the next wear cycle.”

In addition, the following information was provided via email correspondence from the registrant initiated on 4/1/2021:

From: [Blackburn, Tajah](#)
To: [John Gilbert](#)
Cc: [Greg Sarnecki](#); [Bill Schwingel](#); [lahirij@corning.com](#); [Golas, Avantika](#); [Willis, Kristen](#)
Subject: RE: Summary of our meeting on April 1st
Date: Sunday, April 11, 2021 4:17:50 PM

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dr. Gilbert,

Understanding the challenges associated with the negative controls, and similar to other testing scenarios for other non-traditional antimicrobial surfaces, the proposed path forward, as highlighted, below is acceptable.

Regards.

Tajah L. Blackburn, PhD, MPH
LCDR, United States Public Health Service (USPHS)
Senior Scientist, Product Science Branch (PSB)
Antimicrobials Division (AD)
Office of Chemical Safety and Pollution Prevention (OCSP)
Environmental Protection Agency (EPA)
1200 Pennsylvania Ave., N.W. (7510P)
Washington, DC, 20460
703-347-0260 (Office)
571-429-0993 (Cell)

From: John Gilbert <JGILBERT@BEHR.COM>
Sent: Thursday, April 1, 2021 1:18 PM
To: Willis, Kristen <Willis.Kristen@epa.gov>; Blackburn, Tajah <blackburn.tajah@epa.gov>
Cc: Greg Sarnecki <GSARNECKI@BEHR.COM>; Bill Schwingel <BSchwingel@masco-rd.com>; lahirij@corning.com; Golas, Avantika <GolasA@corning.com>
Subject: Summary of our meeting on April 1st

Hello Dr. Willis and Dr. Blackburn:

Thanks for meeting with me and my colleagues on short notice on April 1st.

As we discussed, Behr is preparing submission materials for an antimicrobial/antiviral paint using Corning Guardian (containing CuO) as the active ingredient. We currently have draft reports from

the third-party labs that have done the testing. We will be submitting our data via the EPA electronic portal as soon as we receive the final audited reports. This communication will serve to summarize our discussion.

As we have reviewed the preliminary draft reports, we noted the following:

- Across the entire range of microbes tested (four species of bacteria and four viruses), the paint with Corning Guardian exhibits excellent % kills vs. the uncoated control substrate.
- In some cases, the “control paint” without Corning Guardian has inconsistent or poor recovery of organisms, rendering the comparison of paint with Guardian vs. the paint without Guardian not useful.
- The paint with Guardian always exhibits >99.9% kill in 2 hours vs. the uncoated control substrate (and in most cases a kill percentage several magnitudes beyond that).

When your team reviews the data, you will notice that in every case (across three different third-party labs, eight different microbes, and several variations of paint sheen and color), the paint with Corning Guardian provides a very effective kill. My “ask” is that you give **consideration to the log kill of the paint with Guardian vs. the reference unpainted substrate in those cases in which the “control paint” without Guardian did not provide good recovery of microbes.** As we noted, using uncoated substrate as a reference control has precedence in many antimicrobial test procedures.

I have attached the Powerpoint slides that we reviewed in our call. The slides summarize the data on all eight microbes (five of which we covered in the meeting). You will see that some microbes such as Feline calicivirus or Influenza A are quite robust on the “control paint” without Guardian, but other microbes such as Pseudomonas, VRE or SARS-CoV-2 are fragile (to varying degrees) on the “control paint.”

Most important, when taken as an entire body of data, you will see how effective the paint with Guardian is at killing microorganisms. This is very consistent with the well-known antimicrobial properties of copper alloy surfaces.

Again, thank you for your time on April 1st.

Sincerely,

John Gilbert

Dr. John A. Gilbert
Chief Research and Development Officer
Behr Process Corporation
1801 East St. Andrew Place
Santa Ana, CA 92705
714-545-7101 ext 2329

| | | | |
|---|--|---|---------------------------------|
| 1. | MRID | 51549611 | |
| Study Objective | | Supplemental Residual Antimicrobial Product, Surface Paints – Bacterial | |
| Study Title | | GLP Continuous Bacterial Reduction on Coated Surfaces | |
| Testing Lab; Lab Study ID | | Microchem Laboratory; Study ID: GLP2494-A1 | |
| Experimental Start Date | | 10/5/2020 | Study Completion Date: 4/8/2021 |
| | | | Report Amended Date: 4/23/2021 |
| Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+ | | <i>Staphylococcus aureus</i> (ATCC 6348) | |
| Test Method | | Protocol for the Evaluation of Bactericidal Activity of Antimicrobial Coated Surfaces, Corning Incorporated, MRID 51141401; EPA Memorandum 89661-2_DP457456 | |
| Application Method | | Coat carrier surface | |
| Test Substance Preparation | Name/ID | Behr Eggshell Base Paint and Semi-Gloss Deep Paint | |
| | Lots <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input checked="" type="checkbox"/> 4 | Eggshell Base Paint Lots: 1 and 2 Semi-Gloss Deep Paint Lots: 1 and 2 | |
| | Preparation | Tested concentration: See post-test chemical analysis of test samples listed above Tested Dilution: Ready-to-use Diluent: N/A | |
| Soil load | | 5% Fetal Bovine Serum and 0.01% Triton X-100 solution | |
| Carrier type, # per lot | | 1 x 1 inch painted surfaces; 13 carriers per Lot 1 and 5 carriers per Lot 2 (see table below) | |
| Test conditions | | Contact time: 120 ± 5 minutes Temperature: 21.9 – 23.6°C Relative humidity: 40% - 57% | |
| Neutralizer | | Lethen Broth (20.0 ml) | |
| Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.) | | <p>Protocol Amendments:</p> <ol style="list-style-type: none"> 1. Test Facility Management reassigned the Study Director for this protocol. The protocol was amended to change the Study Director from Hillary Johnson to Nathaniel Garza. <p>Protocol Deviations:</p> <ol style="list-style-type: none"> 1. On 10/9/2020, the plates for the determination of the test culture titer were incubated an additional 2 hours and 32 minutes outside of the protocol-specified 24048 hours. The test culture enumerations were specific to the Neutralization Confirmation Assays conducted on this date. 2. On 10/12/2020, 10/13/2020, 10/14/2020/ 10/15/2020, and 10/16/2020, five test replicates were conducted for unexposed, treated carriers rather than the protocol-specified three. | |

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| | 3. On 10/8/2020, single replicates were tested for the scrub chart viability carrier rather than in triplicate as stated in the protocol. |
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| 2. | MRID | 51549612 | |
| Study Objective | | Supplemental Residual Antimicrobial Product, Surface Paints – Bacterial | |
| Study Title | | GLP Continuous Bacterial Reduction on Coated Surfaces | |
| Testing Lab; Lab Study ID | | Microchem Laboratory; Study ID: GLP2505-A1 | |
| Experimental Start Date | | 10/21/2020 | Study Completion Date: 4/7/2021 |
| | | | Report Amended Date: 4/23/2021 |
| Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+ | | <i>Pseudomonas aeruginosa</i> (ATCC 15442) | |
| Test Method | | Protocol for the Evaluation of Bactericidal Activity of Antimicrobial Coated Surfaces, Corning Incorporated, MRID 51141401; EPA Memorandum 89661-2_DP457456 | |
| Application Method | | Coat carrier surface | |
| Test Substance Preparation | Name/ID | Behr Eggshell Base Paint and Semi-Gloss Deep Paint | |
| | Lots <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input checked="" type="checkbox"/> 4 | Eggshell Base Paint Lots: 1 and 2 Semi-Gloss Deep Paint Lots: 1 and 2 | |
| | Preparation | Tested concentration: See post-test chemical analysis of test samples listed above Tested Dilution: Ready-to-use Diluent: N/A | |
| Soil load | | 5% Fetal Bovine Serum and 0.01% Triton X-100 solution | |
| Carrier type, # per lot | | 1 x 1 inch painted surfaces; 13 carriers per Lot 1 and 5 carriers per Lot 2 (see table below) | |
| Test conditions | | Contact time: 120 ± 5 minutes Temperature: 21.3 – 23.5°C Relative humidity: 36% - 57% | |
| Neutralizer | | Lethen Broth (20.0 ml) | |
| Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.) | | Protocol Amendments: 1. Protocol P2959 was amended to include a step for decanting the test culture after the 18–24-hour incubation period, to remove any traces of the pellicle from the test culture or physical removal of the pellicle prior to gently vortexing the test culture. 2. Test Facility Management reassigned the Study Director for this protocol. The protocol was amended to change the Study Director from Hillary Johnson to Nathaniel Garza. Protocol Deviations: | |

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| | <ol style="list-style-type: none"> 1. During frozen cryovial preparation, a protocol deviation occurred where golden yellow colonies were intentionally not selected for re-suspension into 1.0 ml of Tryptic Soy Broth prior to the inoculation of the final set of plates. Per the study report, this was intentionally done because the microorganism that was being harvested does not have morphological characteristics in line with this description. 2. On 11/4/2020, the plates for the determination of the test culture titer were incubated an additional 24 minutes outside of the protocol-specified 24-48 hours. 3. On 11/2/2020, 10/22/2020, and 10/22/2020, the test articles used on these days were inadvertently used 3, 3, and 2 days, respectively, outside of the protocol-specified week from initial treatment. |
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| 3. | MRID | 51549609 |
| Study Objective | | Supplemental Residual Antimicrobial Product, Surface Paints – Virucidal |
| Study Title | | Evaluation of Antiviral Activity of Surfaces Coated by Antimicrobial Paint – Feline calicivirus |
| Testing Lab; Lab Study ID | | Microbac Laboratories, Inc.; Study ID: 1083-101 |
| Experimental Start Date | | 12/14/2020 |
| | | Study Completion Date: 3/3/2021 |
| Test organism(s) | | Feline calicivirus, Strain F-9 (ATCC VR-782) as a surrogate for Human Norovirus |
| <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+ | | |
| Indicator Cell Culture | | CrFK cells (ATCC CCL-94) |
| Test Method | | Protocol for the Evaluation of Bactericidal Activity of Antimicrobial Coated Surfaces, Corning Incorporated, MRID 51141401; EPA Memorandum 89661-2_DP457456; Protocol Identification Number: BEH.1a.11.04.20 |
| Application Method | | Coat carrier surface |
| Test Substance Preparation | Name/ID | Behr Eggshell Base Paint and Semi-Gloss Deep Paint |
| | Lots | Eggshell Base Paint Lots: 1 and 2 |
| | <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input checked="" type="checkbox"/> 4 | Semi-Gloss Deep Paint Lots: 1 and 2 |
| | Preparation | Tested concentration: See post-test chemical analysis of test samples listed above Tested Dilution: Ready-to-use Diluent: N/A |
| Soil load | | 5% Fetal Bovine Serum (FBS) in viral inoculum |
| Carrier type, # per lot | | 1 x 1 inch painted surfaces; (see table below for carriers per Lot) |
| Test conditions | | Contact time: 120 ± 5 minutes Temperature: 20 – 21°C Relative humidity: 26 – 36% |

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| Neutralizer | Minimum Essential Medium (MEM) + 10% Newborn Calf Serum (NCS) |
| Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.) | <p>Protocol Amendments:</p> <ol style="list-style-type: none"> <i>The Neutralizer effectiveness/Viral interference control (NE/VI) section of the protocol states that each 4.5 mL dilution of the NE/VI control will be spiked with 0.1 mL of low tittered virus. It should state 0.45 mL dilutions will be spiked with 0.01 mL of low titered virus. This amendment serves to correct the volumes used for the NE/VI spike in the Neutralizer effectiveness/Viral interference control (NE/VI) section of the protocol.</i> <i>The protocol mentions test method ASTM method E1053-20, "Standard Test Method to Assess Virucidal Activity of Chemicals Intended for Disinfection of Inanimate, Nonporous Environmental Surfaces". The correct test method is ASTM method E1053-20, "Standard Practice to Assess Virucidal Activity of Chemicals Intended for Disinfection of Inanimate, Nonporous Environmental Surfaces". This amendment serves to correct the test method listed in the protocol.</i> <i>Project Sheet No. 1 lists the active ingredient as Corning Gradient at 0.96 wt% = 3168 ppm Cu. The correct active ingredient is Corning Gradient at 0.96 wt% = 3168 ppm CuO. This amendment serves to correct the active ingredient listed on Project Sheet No. 1.</i> <i>Project Sheet No. 1 lists the following test material information: Unexposed control carrier – 3193, DS No. K1669; Quat-exposed control carrier – 3193, DS No. K1666; Quat-exposed treated carrier – 3193, DS No. K1667 and Unexposed treated carrier – 3193, DS No. K1671. The correct information is Unexposed control carrier – 3193, DS No. K1667; Quat exposed control carrier – 3193, DS No. K1671; Quat-exposed treated carrier – 3193, DS No. K1669 and Unexposed treated carrier – 3193, DS No. K1666. This amendment serves to correct the test material information listed on Project Sheet No. 1.</i> <i>Amendment 1 on Project Sheet No. 1 amends the NE/VI control by reducing the volume by 10-fold. It should therefore also reduce the required quantity of virus in the spike by ten-fold to 100-500 vial units. This amendment serves to expand upon Amendment 1 on Project Sheet No. 1.</i> <i>Project Sheet No. 1 and 2 list the active ingredient as Corning Gradient". It should be listed as "Corning Guardiant". This amendment serves to</i> |

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| | <p><i>correct the active ingredient name listed on Project Sheet No. 1 and 2.</i></p> <p>No Protocol Deviations were reported.</p> |
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| 4. | MRID | 51549610 (Non-GLP) |
| Study Objective | | Supplemental Residual Antimicrobial Product, Surface Paints – Virucidal |
| Study Title | | Efficacy of Behr Antiviral Paints against SARS-CoV-2, Isolate USA-WA1/2020 |
| Testing Lab; Lab Study ID | | Water and Energy Sustainable Technology (WEST) Center; Lab Study ID not provided |
| Experimental Start Date | | 1/21/2021 |
| | | Study Completion Date: 4/22/2021 |
| Test organism(s) | | SARS-CoV-2, Isolate USA-WA1/2020 (Source: BEI Resources NR-52281) |
| <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+ | | |
| Indicator Cell Culture | | Vero E6 (African Green Monkey kidney) cells (ATCC CRL-1586) |
| Test Method | | Protocol for the Evaluation of Bactericidal Activity of Antimicrobial Coated Surfaces, Corning Incorporated, MRID 51141401; EPA Memorandum 89661-2_DP457456 |
| Application Method | | Two coats of paint are applied using the standard drawdown technique and allowed to dry for ≥24 hours. |
| Test Substance Preparation | Name/ID | Behr Eggshell Base Paint and Semi-Gloss Deep Paint |
| | Lots | Eggshell Base Paint Lots: 1 and 2 |
| | <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input checked="" type="checkbox"/> 4 | Semi-Gloss Deep Paint Lots: 1 and 2 |
| | Preparation | Tested concentration: See post-test chemical analysis of test samples listed above Tested Dilution: Ready-to-use Diluent: N/A |
| Soil load | | 5% Fetal Bovine Serum (FBS) in viral inoculum |
| Carrier type, # per lot | | 1 x 1 inch painted surfaces; (see table below for carriers per Lot) |
| Test conditions | | Contact time: 120 ± 5 minutes Temperature: 20°C Relative humidity: 50% |
| Neutralizer | | Sephadex™ G-10 columns |
| Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.) | | <p>No Protocol Amendments or Protocol Deviations were reported.</p> <p>Notes:</p> <ul style="list-style-type: none"> Non-GLP Study – deviations form GLP standards are included on page 3 of the report. |

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| | <ul style="list-style-type: none">• Uncoated scrub chart panels were used as a test viability control. |
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IV STUDY RESULTS

Table 1. Lots 1 and 2 – *Staphylococcus aureus* (ATCC 6538)

Lot 1 = Simulated Wear Cycles; Lot 2 = No Wear Cycles

Tint and Treatment Descriptions: Untreated (Control Surfaces) = without Copper; Treated = with Copper; Unexposed = without Wear Cycles

Note: Cleaner 3 / 3% Hydrogen Peroxide (Not tested)

| MRID | Organism | Formulation ID Code | Lot | Test Date | Results | | | | | | Scrub Chart Log ₁₀ Recovery |
|----------------------|-----------------------------------|--------------------------------|-----|------------|--|---|---|---|---|--|--|
| | | | | | Exposure Type | Average Recovery (Log ₁₀ /carrier) (Untreated) | Log ₁₀ Reduction (Untreated, Unexposed comparison) | Log ₁₀ Reduction (Treated, Unexposed comparison) | Percent Reduction (Control – Treated, Exposed comparison) | Percent Reduction (Viability – Scrub Chart comparison) | |
| 2-hour exposure time | | | | | | | | | | | |
| 51549611 | Staphylococcus aureus (ATCC 6538) | Eggshell Base Paint (Untinted) | 1 | 10/12/2020 | No Cleaner/ No Wear Cycles (Unexposed) | 4.98 | N/A | N/A | 99.9895% | ≥ 99.99991% | 7.06 |
| | | | | | Cleaner 1 / (Quat) | 1.93 | 3.05 | 0.00 | 88.25% | ≥ 99.99991% | |
| | | | | | Cleaner 2 / (Cleaner) | 5.43 | - 0.45 | 0.00 | 99.997% | ≥ 99.99991% | |
| | | | 2 | 10/19/2020 | No Cleaner/ No Wear Cycles (Unexposed) | 5.53 | N/A | N/A | 99.997% | ≥ 99.99994% | 7.27 |
| | | Organic Pigment (Tinted) | 1 | 10/16/2020 | No Cleaner/ No Wear Cycles (Unexposed) | 5.44 | N/A | N/A | ≥ 99.996% | ≥ 99.999902% | 7.01 |
| | | | | | Cleaner 1 / (Quat) | ≤ 1.00 | ≥ 4.44 | 0.00 | 0.00% | ≥ 99.999902% | |
| | | | | | Cleaner 2 / (Cleaner) | 4.95 | 0.49 | 0.00 | ≥ 99.9888% | ≥ 99.999902% | |
| | | | 2 | 10/20/2020 | No Cleaner/ No Wear Cycles (Unexposed) | 6.39 | N/A | N/A | ≥ 99.9996% | ≥ 99.99994% | 7.21 |
| | | Inorganic Pigment (Tinted) | 1 | 10/15/2020 | No Cleaner/ No Wear Cycles (Unexposed) | 6.20 | N/A | N/A | ≥ 99.9994% | ≥ 99.99996% | 7.35 |
| | | | | | Cleaner 1 / (Quat) | ≤ 1.00 | ≥ 5.20 | 0.00 | 0.00% | ≥ 99.99996% | |

| MRID | Organism | Formulation ID Code | Lot | Test Date | Results | | | | | | Scrub Chart Log ₁₀ Recovery |
|----------------------|----------|-------------------------------|------------|--|--|---|---|---|---|--|--|
| | | | | | Exposure Type | Average Recovery (Log ₁₀ /carrier) (Untreated) | Log ₁₀ Reduction (Untreated, Unexposed comparison) | Log ₁₀ Reduction (Treated, Unexposed comparison) | Percent Reduction (Control – Treated, Exposed comparison) | Percent Reduction (Viability – Scrub Chart comparison) | |
| 2-hour exposure time | | | | | | | | | | | |
| | | | | | Cleaner 2 / (Cleaner) | 6.10 | 0.10 | 0.00 | ≥ 99.9992% | ≥ 99.99996% | |
| | | | 2 | 10/19/2020 | No Cleaner/ No Wear Cycles (Unexposed) | 6.66 | N/A | N/A | ≥ 99.9998% | ≥ 99.99994% | 7.27 |
| | | Carbon Black Pigment (Tinted) | 1 | 10/14/2020 | No Cleaner/ No Wear Cycles (Unexposed) | 5.77 | N/A | N/A | ≥ 99.995% | ≥ 99.9998% | 7.28 |
| | | | | | Cleaner 1 / (Quat) | ≤ 1.00 | ≥ 4.77 | 0.00 | 0.00% | ≥ 99.99995% | |
| | | | | | Cleaner 2 / (Cleaner) | 5.23 | 0.54 | 0.00 | ≥ 99.994% | ≥ 99.994% | |
| | | 2 | 10/20/2020 | No Cleaner/ No Wear Cycles (Unexposed) | 6.28 | N/A | N/A | ≥ 99.9995% | ≥ 99.99994% | 7.21 | |
| | | Semi-Gloss Deep (Untinted) | 1 | 10/13/2020 | No Cleaner/ No Wear Cycles (Unexposed) | 3.26 | N/A | N/A | ≥ 99.45% | ≥ 99.99992% | 7.12 |
| | | | | | Cleaner 1 / (Quat) | ≤ 1.00 | ≥ 2.26 | 0.00 | 0.00% | ≥ 99.99992% | |
| | | | | | Cleaner 2 / (Cleaner) | 6.01 | - 2.75 | ≥ 2.27 | 99.82% | ≥ 99.986% | |
| | | | 2 | 10/20/2020 | No Cleaner/ No Wear Cycles (Unexposed) | 4.32 | N/A | N/A | 99.86% | ≥ 99.9997% | 7.21 |

Table 2. Lots 1 and 2 – *Pseudomonas aeruginosa* (ATCC 15442)

Lot 1 = Simulated Wear Cycles; Lot 2 = No Wear Cycles

Tint and Treatment Descriptions: Untreated (Control Surfaces) = without Copper; Treated = with Copper; Unexposed = without Wear Cycles

Note: Cleaner 3 / 3% Hydrogen Peroxide (Not tested)

| MRID | Organism | Formulation ID Code | Lot | Test Date | Results | | | | | | Scrub Chart Log ₁₀ Recovery |
|----------------------|--|---|-----|------------|--|---|---|---|---|--|--|
| | | | | | Exposure Type | Average Recovery (Log ₁₀ /carrier) (Untreated) | Log ₁₀ Reduction (Untreated, Unexposed comparison) | Log ₁₀ Reduction (Treated, Unexposed comparison) | Percent Reduction (Control – Treated, Exposed comparison) | Percent Reduction (Viability – Scrub Chart comparison) | |
| 2-hour exposure time | | | | | | | | | | | |
| 51549612 | <i>Pseudomonas aeruginosa</i> (ATCC 15442) | Eggshell Base Paint (Untinted) | 1 | 10/26/2020 | No Cleaner/ No Wear Cycles (Unexposed) | 5.16 | N/A | N/A | ≥ 99.993% | ≥ 99.9996% | 6.38 |
| | | | | | Cleaner 1 / (Quat) | 5.44 | - 0.28 | 0.00 | ≥ 99.996% | ≥ 99.9996% | |
| | | | | | Cleaner 2 / (Cleaner) | 6.21 | - 1.05 | 0.00 | ≥ 99.9994% | ≥ 99.9996% | |
| | | | 2 | 10/22/2020 | No Cleaner/ No Wear Cycles (Unexposed) | 5.61 | N/A | N/A | 99.998% | ≥ 99.9996% | 6.41 |
| | | | | | | | | | | | |
| | | | | | | | | | | | |
| | | Eggshell Base Paint with Organic Pigment (Tinted) | 1 | 10/30/2020 | No Cleaner/ No Wear Cycles (Unexposed) | 1.37 | N/A | N/A | ≥ 57.26% | ≥ 99.9998% | 6.72 |
| | | | | | Cleaner 1 / (Quat) | 4.92 | - 3.55 | 0.00 | ≥ 99.988% | ≥ 99.9998% | |
| | | | | | Cleaner 2 / (Cleaner) | 4.88 | - 3.51 | 0.00 | ≥ 99.987% | ≥ 99.9998% | |
| | | | 2 | 10/23/2020 | No Cleaner/ No Wear Cycles (Unexposed) | 2.34 | N/A | N/A | ≥ 95.43% | ≥ 99.9994% | 6.20 |
| | | | | | | | | | | | |
| | | | | | | | | | | | |
| | | Eggshell Base Paint with Inorganic Pigment (Tinted) | 1 | 11/2/2020 | No Cleaner/ No Wear Cycles (Unexposed) | 3.81 | N/A | N/A | ≥ 99.8% | ≥ 99.9998% | 6.72 |
| | | | | | Cleaner 1 / (Quat) | 6.44 | - 2.63 | 0.00 | ≥ 99.9996% | ≥ 99.99996% | |
| | | | | | Cleaner 2 / (Cleaner) | 5.62 | - 1.81 | 0.00 | ≥ 99.998% | ≥ 99.99996% | |

| MRID | Organism | Formulation ID Code | Lot | Test Date | Results | | | | | | Scrub Chart Log ₁₀ Recovery |
|----------------------|----------|--|-----|------------|--|---|---|---|---|--|--|
| | | | | | Exposure Type | Average Recovery (Log ₁₀ /carrier) (Untreated) | Log ₁₀ Reduction (Untreated, Unexposed comparison) | Log ₁₀ Reduction (Treated, Unexposed comparison) | Percent Reduction (Control – Treated, Exposed comparison) | Percent Reduction (Viability – Scrub Chart comparison) | |
| 2-hour exposure time | | | | | | | | | | | |
| | | Eggshell Base Paint with Carbon Black Pigment (Tinted) | 2 | 10/23/2020 | No Cleaner/ No Wear Cycles (Unexposed) | 2.34 | N/A | N/A | ≥ 95.43% | ≥ 99.9994% | 6.20 |
| | | | 1 | 10/29/2020 | No Cleaner/ No Wear Cycles (Unexposed) | 3.41 | N/A | N/A | ≥ 99.61% | ≥ 99.9997% | 6.57 |
| | | | | | Cleaner 1 / (Quat) | 4.86 | - 1.45 | 0.00 | ≥ 99.986% | ≥ 99.9997% | |
| | | | | | Cleaner 2 / (Cleaner) | 5.53 | - 2.12 | 0.00 | ≥ 99.997% | ≥ 99.9997% | |
| | | | 2 | 10/22/2020 | No Cleaner/ No Wear Cycles (Unexposed) | 5.26 | N/A | N/A | ≥ 99.995% | ≥ 99.9996% | 6.41 |
| | | Semi-Gloss Deep | 1 | 10/27/2020 | No Cleaner/ No Wear Cycles (Unexposed) | ≤ 1.00 | N/A | N/A | 0.00% | ≥ 99.9994% | 6.24 |
| | | | | | Cleaner 1 / (Quat) | 3.77 | ≤ - 2.77 | 0.00 | ≥ 99.8% | ≥ 99.9994% | |
| | | | | | Cleaner 2 / (Cleaner) | 4.09 | ≤ - 3.09 | 0.00 | ≥ 99.92% | ≥ 99.9994% | |
| | | | | | 2 | 10/21/2020 | No Cleaner/ No Wear Cycles (Unexposed) | 5.76 | N/A | N/A | |

Table 3. Lots 1 and 2 – Feline calicivirus, Strain F-9 (ATCC VR-782) as a surrogate for Human Norovirus

Lot 1 = Simulated Wear Cycles; Lot 2 = No Wear Cycles

Average of 2 replicates for unexposed coupons and treated coupons

Tint and Treatment Descriptions: Untreated = without Copper; Treated = with Copper; Unexposed = without Wear Cycles

*No virus was detected; the theoretical titer was determined based on the Poisson method

Notes:

-Per the recommended protocol, Sodium Hypochlorite, Hydrogen Peroxide, and EDTA/phosphoric acid solutions were not tested

-Scrub chart comparison not provided (Untreated = without Copper)

-Viral load from the unexposed, treated control carriers were used as the input load to calculate log reduction.

-Results for untreated carriers were not provided

-Individual test dates for carriers not provided

Individual test dates for carriers not provided

| MRID | Organism | Formulation ID Code | Lot | Results | | | | Population Control (TCID ₅₀ Log ₁₀ / carrier) |
|----------------------|--|--|-----|--|--|---|---|---|
| | | | | Exposure Type | Average Input Load (Log ₁₀ TCID ₅₀ / carrier)* | Average Output Load (Log ₁₀ TCID ₅₀ / carrier)* | Log ₁₀ Reduction (Treated, Unexposed comparison) | |
| 2-hour exposure time | | | | | | | | |
| 51549609 | Feline calicivirus, Strain F-9 (ATCC VR-782) | Eggshell Base Paint (Untinted) / 2190 | 1 | No Cleaner/ No Wear Cycles (Unexposed) | 4.99 | ≤ 0.83 | ≥ 4.16 | 5.24 |
| | | | | Cleaner 2 / (Quat) | 4.87 | ≤ 1.83 | ≥ 3.04 | |
| | | | | Cleaner 1 / (Cleaner) | 5.12 | ≤ 0.83 | ≥ 4.29 | |
| | | | 2 | No Cleaner/ No Wear Cycles (Unexposed) | 4.93 | ≤ 0.83 | ≥ 4.10 | |
| | | Eggshell Base Paint with Organic Pigment (Tinted) / 2190-O | 1 | No Cleaner/ No Wear Cycles (Unexposed) | 4.93 | ≤ 0.83 | ≥ 4.10 | |
| | | | | Cleaner 2 / (Quat) | 5.05 | ≤ 1.83 | ≥ 3.22 | |
| | | | | Cleaner 1 / (Cleaner) | 4.99 | ≤ 0.83 | ≥ 4.16 | |
| | | | 2 | No Cleaner/ No Wear Cycles (Unexposed) | 4.93 | ≤ 0.83 | ≥ 4.10 | |
| | | Eggshell Base Paint with Inorganic Pigment (Tinted) / 2190-I | 1 | No Cleaner/ No Wear Cycles (Unexposed) | 5.06 | ≤ 0.83 | ≥ 4.23 | |
| | | | | Cleaner 2 / (Quat) | 4.87 | ≤ 1.83 | ≥ 3.04 | |
| | | | | Cleaner 1 / (Cleaner) | 4.87 | ≤ 0.83 | ≥ 4.04 | |

| MRID | Organism | Formulation ID Code | Lot | Results | | | | Population Control (TCID ₅₀ Log ₁₀ / carrier) |
|----------------------|----------|---|-----|--|--|---|---|---|
| | | | | Exposure Type | Average Input Load (Log ₁₀ TCID ₅₀ / carrier)* | Average Output Load (Log ₁₀ TCID ₅₀ / carrier)* | Log ₁₀ Reduction (Treated, Unexposed comparison) | |
| 2-hour exposure time | | | | | | | | |
| | | | 2 | No Cleaner/ No Wear Cycles (Unexposed) | 5.05 | ≤ 0.83 | ≥ 4.22 | |
| | | Eggshell Base Paint with Carbon Black Pigment (Tinted) / 2190-B | 1 | No Cleaner/ No Wear Cycles (Unexposed) | 4.99 | ≤ 0.83 | ≥ 4.16 | |
| | | | | Cleaner 2 / (Quat) | 5.06 | ≤ 1.83 | ≥ 3.23 | |
| | | | | Cleaner 1 / (Cleaner) | 4.99 | ≤ 0.83 | ≥ 4.16 | |
| | | | 2 | No Cleaner/ No Wear Cycles (Unexposed) | 4.93 | ≤ 0.83 | ≥ 4.10 | |
| | | Semi-Gloss Deep / 3193 | 1 | No Cleaner/ No Wear Cycles (Unexposed) | 4.93 | ≤ 0.83 | ≥ 4.10 | |
| | | | | Cleaner 2 / (Quat) | 4.99 | ≤ 1.83 | ≥ 3.16 | |
| | | | | Cleaner 1 / (Cleaner) | 4.93 | ≤ 0.83 | ≥ 4.10 | |
| | | | 2 | No Cleaner/ No Wear Cycles (Unexposed) | 5.06 | ≤ 0.83 | ≥ 4.23 | |

Table 4. Lots 1 and 2 – SARS-CoV-2, Isolate USA-WA1/2020 (Source: BEI Resources NR-52281)

Tint and Treatment Descriptions: Untreated (Control Surfaces) = without Copper; Treated = with Copper; Unexposed = without Wear Cycles

Note: Per the recommended protocol, Sodium Hypochlorite, Hydrogen Peroxide, and EDTA/phosphoric acid solutions were not tested

| MRID (Test Date) | Organism | Formulation ID Code | Lot | Tint and Treatment Description | Results | | | Scrub Chart Log ₁₀ Recovery | Population Control (TCID ₅₀ Log ₁₀ / carrier) |
|--------------------------------------|---|---|-----|-----------------------------------|---|---|---|--|---|
| | | | | | Average Recovery (Log ₁₀ / carrier) | Log ₁₀ Reduction (Untreated, Unexposed comparison) | Log ₁₀ Reduction (Scrub Chart comparison) | | |
| 2-hour exposure time; No Wear Cycles | | | | | | | | | |
| 51549610 (1/27/2021) | SARS-CoV-2, Isolate USA- WA1/2020 (Source: BEI Resources NR-52281) | Eggshell Base Paint (Untinted) / 2190 | 1 | Untinted, without Copper | < 2.58 | N/A | > 0.75 | 6.25 | 6.17 |
| | | | | Untinted with Copper | < 1.50 | > 4.00 | > 4.75 | | |
| | | | 2 | Untinted, without Copper | 5.08 | N/A | 1.08 | 6.17 | 6.33 |
| | | | | Untinted with Copper | < 1.50 | > 4.58 | > 4.67 | | |
| | | Eggshell Base Paint with Organic Pigment (Tinted) / 2190-O | 1 | Untinted, without Copper | < 1.50 | N/A | > 4.75 | 6.25 | 6.17 |
| | | | | Untinted with Copper | < 1.50 | 0.00 | > 4.75 | | |
| | | | 2 | Untinted, without Copper | < 1.50 | N/A | > 4.67 | 6.17 | 6.33 |
| | | | | Untinted with Copper | < 1.50 | 0.00 | > 4.67 | | |
| | | Eggshell Base Paint with Inorganic Pigment (Tinted) / 2190-I | 1 | Untinted, without Copper | < 1.50 | N/A | > 4.75 | 6.25 | 6.17 |
| | | | | Untinted with Copper | < 1.50 | 0.00 | > 4.75 | | |
| | | | 2 | Untinted, without Copper | < 1.50 | N/A | > 4.67 | 6.17 | 6.33 |
| | | | | Untinted with Copper | < 1.50 | 0.00 | > 4.67 | | |
| | | Eggshell Base Paint with Carbon Black Pigment | 1 | Untinted, without Copper | < 1.50 | N/A | > 4.75 | 6.25 | 6.17 |
| | | | | Untinted with Copper | < 1.50 | 0.00 | > 4.75 | | |

| MRID (Test Date) | Organism | Formulation ID Code | Lot | Tint and Treatment Description | Results | | | Scrub Chart Log ₁₀ Recovery | Population Control (TCID ₅₀ Log ₁₀ / carrier) |
|---------------------|----------|---------------------------|-----|-----------------------------------|---|---|---|--|---|
| | | | | | Average Recovery (Log ₁₀ / carrier) | Log ₁₀ Reduction (Untreated, Unexposed comparison) | Log ₁₀ Reduction (Scrub Chart comparison) | | |
| | | (Tinted) / 2190-B | 2 | Untinted, without Copper | < 1.50 | N/A | > 4.67 | 6.17 | 6.33 |
| | | | | Untinted with Copper | < 1.50 | 0.00 | > 4.67 | | |
| | | Semi-Gloss Deep / 3193 | 1 | Untinted, without Copper | 5.08 | N/A | 1.17 | 6.25 | 6.17 |
| | | | | Untinted with Copper | < 1.50 | > 3.58 | > 4.75 | | |
| | | | 2 | Untinted, without Copper | 5.25 | N/A | 0.92 | 6.17 | 6.33 |
| | | | | Untinted with Copper | < 1.50 | > 3.75 | > 4.67 | | |

V STUDY CONCLUSIONS

| MRID | Claim | Surface Type | Application Method(s) and Dilution | Contact Time | Soil load | Diluent | Organism(s) | Data support tested conditions? |
|--------------------|---|-------------------------|--|--------------|--------------------------|---------|--|---------------------------------|
| 51549611, 51549612 | Supplemental antimicrobial residual copper paint, bacterial | Hard non-porous surface | Applied using the standard drawdown technique and allowed to dry for ≥24 hours; Ready-to-Use | 2 hours | 5% FBS + 1% Triton X-100 | N/A | <ul style="list-style-type: none"> • <i>Staphylococcus aureus</i> (ATCC 6348) • <i>Pseudomonas aeruginosa</i> (ATCC 15442) | Yes |
| 51549609, 51549610 | Supplemental antimicrobial residual copper paint, viral | Hard non-porous surface | Applied using the standard drawdown technique and allowed to dry for ≥24 hours; Ready-to-Use | 2 hours | 5% FBS | N/A | <ul style="list-style-type: none"> • Feline calicivirus, Strain F-9 (ATCC VR-782) as a surrogate for Human Norovirus • SARS-CoV-2, Isolate USA-WA1/2020 (Source: BEI Resources NR-52281) | Yes |

VI LABEL COMMENTS

Label Date/Identification Number: April 23, 2021, Label Version 1

Note: If neither are available, a copy of the label version under review should be inserted into the review document.

1. The proposed label claims that the product, Behr Sanitizing Paint, EPA Reg. No. 32273-RN, when applied as a ready-to-use architectural coating/ paint, in the following pigments:

Eggshell Base Paint
Eggshell Base Paint with Organic Pigment
Eggshell Base Paint with Inorganic Pigment
Eggshell Base Paint with Carbon Black Pigment
Semi-Gloss Deep

is an effective supplemental residual antimicrobial product against the following on hard, non-porous surfaces for a 2-hour contact time:

Staphylococcus aureus (ATCC 6348)
Pseudomonas aeruginosa (ATCC 15442)
Feline calicivirus, Strain F-9 (ATCC VR-782)
SARS-CoV-2, Isolate USA-WA1/2020 (Source: BEI Resources NR-52281)

These claims are **acceptable** as they are supported by the submitted data. It should be noted that Certificates of Analysis (CoAs) for the post-test analysis of the test product samples indicate that Eggshell Base Paint with organic pigment was above the lower certified limit listed on the CSF for the subject product dated 4/28/2021. However, due to the collective data presented, the Agency will accept the aforementioned claims for this pigment. Note that this the only time the Agency will extend this provision and for any future data submissions, the Agency will only accept the chemical analysis of test lots performed prior to the initiation of testing.

2. The following Conditions of Registration should be included consistent with the efficacy review for the Protocol for the Evaluation of Bactericidal Activity of Antimicrobial Coated Surfaces, Corning Incorporated, MRID 51141401; EPA Memorandum 89661-2_DP457456.

The Conditions of Registration, as detailed below, are a requirement for registration to include determination of chemicals incompatible with surfaces from use:

Conditions of Registration

The following are a listing of Conditions of Registration required to support the proposed claims and use patterns:

Condition 1

The registrant will prepare and implement a stewardship program to support the responsible use of antimicrobial surface products. The Plan will be submitted for EPA review and approval within two months after the registration date. If EPA determines at any time after 18 months following registration that the Plan is not being adequately or

timely implemented or that implementation of the Plan is not effectively ensuring the proper sale, distribution, or use of antimicrobial coated surfaces, the registration may be automatically canceled by the Agency by order with opportunity for a hearing but only after notification to the Registrant and an opportunity to meet with the Director of the Office of Pesticide Programs.

The Plan will include, at a minimum, the following elements:

(a) Outreach to the infection control community, including,

- (i) A goal of educating and reinforcing, for infection control professional and other product users, the proper use of the product.
- (ii) Written (including electronic) communications directed to associations of infection control professionals, including at least the APIC, AHE, and any other relevant organizations identified by EPA, and State Departments of Health.
- (iii) Outreach communications will be sent within six months after the date of registration and within one year after the date of registration, and then annually thereafter on the anniversary of the date of registration unless more frequent outreach is deemed necessary.
- (iv) The content of the outreach communications will include statements explaining the registered claims and applications of antimicrobial coated surfaces, as well as their proper use. Additional content of outreach efforts will be developed as part of the Working Group activities.

(b) Development of Website

- (i) The website will serve as a resource for conveying accurate information to the public about the efficacy and proper use of the product.
- (ii) The website will include information on proper labeling and claims (including advertising); supporting science; applications; maintenance; and federal and state regulations and statutory requirements.
- (iii) A question and answer of Frequently Asked Questions (FAQs) section will be incorporated to address common issues or questions raised with regard to the product.
- (iv) The website also serves as a forum to correct any false or misleading third-party statements or publications, including scientific papers, concerning the product. Any such false or misleading third-party statements or publications will be corrected promptly after the registrant becomes aware of such and the responsive website update will be incorporated promptly thereafter. The registrant will inform EPA within 30 calendar days following its receipt of any such false or misleading third-party statements or publications and at the same time provide the Agency with a copy of such statement or publication along with a hard copy of the Website entry correcting such statement or publication.
- (v) The registrant will arrange for and establish links between the website and the websites of appropriate infection control organization, including but not limited to APIC and ASHES.

(c) Establishment/Participation

- (i) Invited participants will include manufacturers, component makers, and representatives from the infection control community, including appropriate trade associations (e.g. APIC and AHE) and State Departments of Health.
- (ii) The Working Group will meet at least twice a year, either in person or by live video conferencing or teleconference.
- (iii) The Working Group will serve as a forum to expand educational efforts, develop outreach communications, and address any questions or concerns from the public and infection control community.

(iv) The registrant will provide the Agency with minutes of any such meetings within 60 days of the end of any such meeting.

3. Make the following changes to the proposed label:

- a. Throughout the label,
 - i. Remove brackets from each instance of “painted surfaces”.
 - ii. Qualify each instance of “Painted surfaces kill 99.9% of bacteria and viruses”, “Painted surfaces kill bacteria and viruses”, “Kills 99.9% of bacteria and viruses”, and similar claims with “within 2 hours of exposure when used as part of a comprehensive infection control program/protocol.”
 - iii. All references to “cleaning” should be expanded to “cleaning/disinfecting” as the product is a supplement to proper cleaning **AND** disinfecting.
- b. Revise the bullets (pages 2 and 3), revise “This product does not replace your current cleaning protocols; clean surfaces with typical cleaning agents in use today” and similar claims to include adverse cleaners/disinfectants with incompatible chemistries. These claims should be combined with the statement “DO NOT USE OXIDIZING CLEANERS/**DISINFECTANTS**, SUCH AS BLEACH AND **HYDROGEN PEROXIDE**, OR ENZYME-BASED CLEANING/DISINFECTING SOLUTIONS AS THEY WILL CAUSE DISCOLORATION AND REDUCE THE EFFICACY OF THE SURFACE. (Note: Requested additions are included in **bold**). Provide clarity to the end user for how surfaces should be treated and how the use application of the subject product may impact cleaning protocols. The cleaners/disinfectants tested do not represent all the typical cleaning agents currently in use.
- c. On pages 4, 5, and 6,
 - i. Remove “antiviral”, “viral-fighting”, “bacterial-fighting”, “harmful”, “pathogenic”, “disease causing”, “difficult to treat”, “power to”, “attacks”, and “premium quality” as these terms are misleading to end users and may imply heightened efficacy activity per the Label Review Manual. Additionally, Per Chapter 12 of the Agency’s Label Review Manual, disease prevention/control claims are under FDA jurisdiction.
 - ii. Remove “microbiocidal” as this term is overly broad.
 - iii. Remove “common” as this term is vague. Organism and viral claims are specific to those listed on the label.
 - iv. Remove “viruses including Coronaviruses” as data were not submitted to substantiated efficacy claims for all Coronaviruses.
- d. On page 5,
 - i. Remove “[combat] [control] [prevent the spread of]” and similar statements related to cross-contamination for consistency with the required label statements for copper-based products.
 - ii. Remove all “sanitize” claims as this product does not meet EPA’s efficacy standards to qualify as a stand-alone disinfectant or sanitizer”.
 - iii. Revise “By killing [pathogenic] [disease causing] [harmful] bacteria on painted surfaces, helps support customers’ environmental [infection] control [teams] [efforts] [practices]” to read “By killing bacteria on painted surfaces within 2 hours of exposure when used as part of a customers’ comprehensive infection control program/protocol [teams] [efforts] [practices].” In addition, brackets should be removed from “infection control”.

- iv. Remove or revise “[Product Name] puts walls and painted surfaces to work as part of an overall cleaning and disinfection strategy [solution]” as this statement may be misleading to end users.
- e. On page 6, revise “SARS-CoV-2 and Feline calicivirus (EPA proxy for Human Noroviruses, Staphylococcus aureus (Staph) and Pseudomonas aeruginosa)” to read “SARS-CoV-2 and Feline calicivirus (EPA proxy for Human Noroviruses), Staphylococcus aureus (Staph) and Pseudomonas aeruginosa.”